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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/066,320	01/31/2002	Jonathan S. Stamler	1818.1030-003	1921

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EXAMINER

GUPTA, ANISH

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 11/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/066,320

Applicant(s)

STAMLER ET AL.

Examiner

Anish Gupta

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) 1-3 and 7-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 4-6 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 7-14-03.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

**DETAILED ACTION*****Election/Restrictions***

1. Applicant's election with traverse of Group III in the reply filed on 9-17-04 is acknowledged. The traversal is on the ground(s) that it had not been demonstrated that the groups are independent. Applicants argue that the restriction requirement did not demonstrate that there would be undue burden to search the separate claims presented. Applicants state that the restriction "has not demonstrated 'various' classification under which these claims allegedly fall." Applicants state that Group IV should, at the very least, be grouped together with Group III since they are not listed in separate class and subclass. Thus, an art related search to the claims of Group III would reveal the related claims of Group IV.

This is not found persuasive because the different classification is not the sole basis for making or withdrawing a restriction requirement. The mere fact that that two independent invention may fall within one subclass does not lead to the conclusion they are not independent inventions. As stated in the previous office action, a search would not only be carried out based on classification but also terms in numerous patent and literature databases. A search a method of deliver of NO to tissue using dinitrosyl iron complex of hemoglobin does not lead to the same results of producing S-nitrosohemoglobin using NO and oxyhemoglobin. A similar problem exists between Group III and Group IV. Group III utilizes oxygenated erythrocytes, while group IV utilizes deoxygenated erythrocytes. An independent search would have to be conducted based on whether the erythrocytes were oxygenated or deoxygenated. If art was furnished for oxygenated erythrocytes, Applicants would not accept that this art render obvious deoxygenated erythrocytes. A perfect illustration of the divergent search strategy is established US Patent 6,153,186. A search for

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oxygenated erythrocytes yielded this patent. This patent however does not implicate deoxygenated erythrocytes. Thus a simple search for Group III was not co-extensive to yield Group IV.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-3, 7-29 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Groups I-II and IV-XVIII, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 9-17-04.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

1. Claims 4 is rejected under 35 U.S.C. 102(b) as being anticipated by Jia et al (Nature).

The claims are drawn to a method of producing S-nitrosohemoglobin by adding NO to a composition comprising oxyhemoglobin.

The reference discloses that incubation of oxyhemoglobin with nitric oxide containing compounds such as GSNO or CYSNO resulted in S-nitrosohemoglobin formation (see page 222). The reference discloses that the S-nitrosylation of Hb were markedly dependant on the conformational state. The Oxy conformation, S-nitrosylation was faster than other conformation (see page 222). Thus reference anticipates the claimed invention.

2. Claims 5-6 are rejected under 35 U.S.C. 102(e) as being anticipated by Stamler et al (US 6153186).

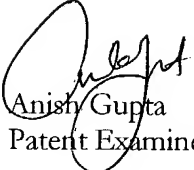
The reference is drawn to method of producing a composition comprising intraerythrocytic NO by adding NO to a composition comprising oxygenated erythrocytes.

The reference disclose the incubation of rat erythrocytes with S-Nitrocysteine, a nitric oxide donor (see col. 16, lines 55-65). Note that the US patent states that rapid incubation of oxygenated rat erythrocytes with nitrosocysteine leads to rapid formation of S-nitrosohemoglobin (see col. 12, lines 8-14). This SNO-Hb formed is intraerythrocytic (see col. 12, lines 11). The reference, therefore, anticipates the claimed invention.

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (571)272-0965. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can normally be reached on (571) 272-0974. The fax phone number of this group is (703) 308-4242.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

 11/22/04  
Anish Gupta  
Patent Examiner